REACH: the New European Chemicals Legislation

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Registration, Evaluation, Authorization, and Restriction of Chemicals

REACH

- Most significant body of chemical regulation to be enacted in more than 20 years.
- Although it is a European legislation, the global nature of chemical production and manufacturing ensures that it will have widespread impacts throughout the world, including California.
- It is estimated to involve 30,000 chemicals and many of the products that contain them.

European Chemical Industry

- One of the largest manufacturing industries in the European Union (EU) directly employing 1.9 million people.
- In 2004, the European chemicals sales amounted to $800 billion. [Those of the US totaled $566 billion.]
- Chemical exposures are a major cause for concern for many Europeans, particularly those from Scandinavian countries.

Existing European Chemical Regulation

- Patchwork system involving ~60 laws
- Primary law (EC 793/93) was enacted in 1981 and created a two tier system.
  - For 100,000 existing chemicals, no testing was required.
  - For new chemicals (>10 kg), substantial testing is required.
- Broadly perceived by Europeans as having serious weaknesses.

REACH Chronology

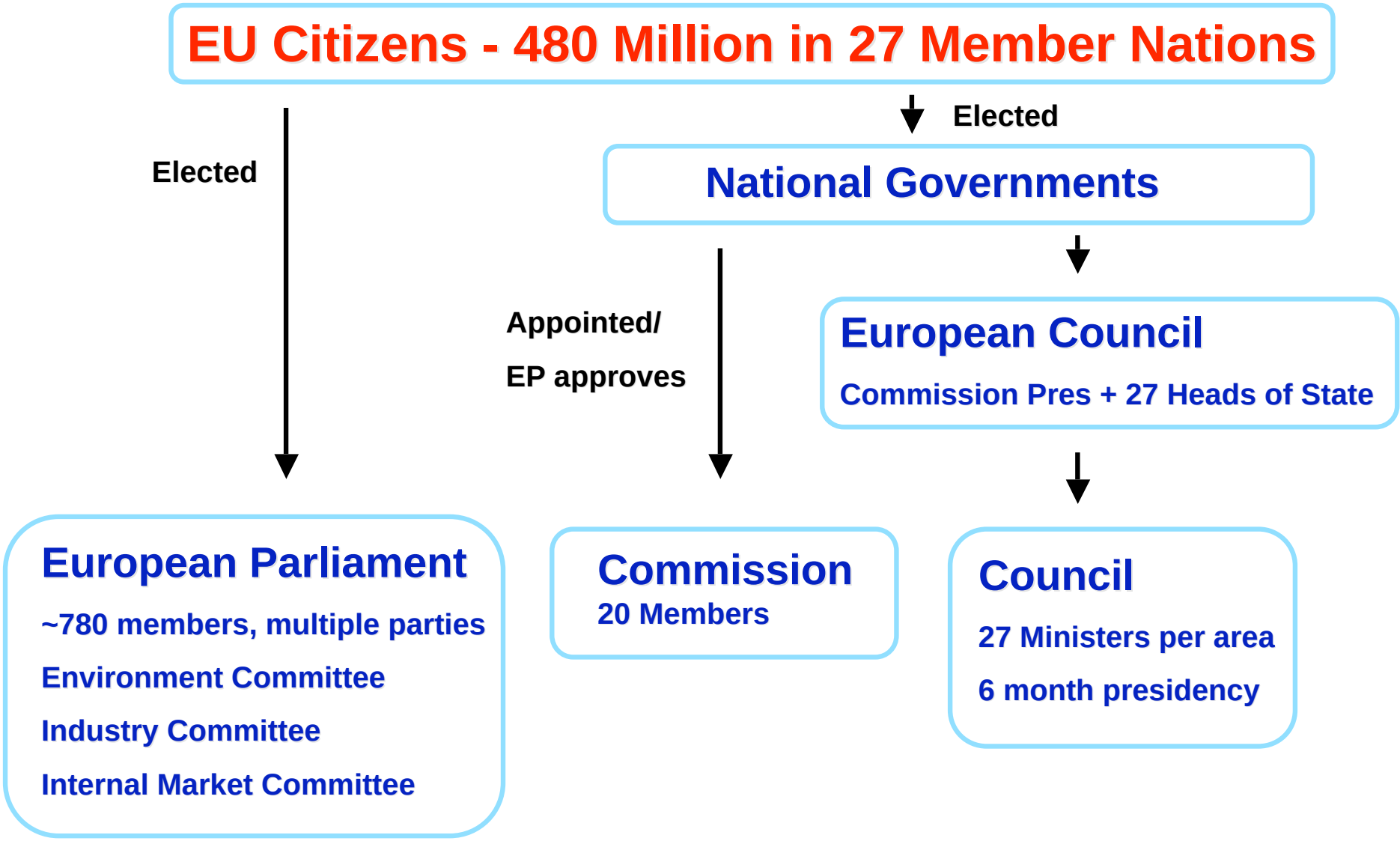
Europe

- 1998-99 Working group established
- 2001 White paper and draft legislation published
- 2003 Commission proposed legislation

United States

- 1984 NRC study on toxicity testing
- 1997 Environmental Defense publishes Toxic Ignorance
- 1998 HPV Challenge program initiated
- 2002 USG initiates vigorous effort to oppose REACH

Legislative Bodies within the European Union



Position of US Government

- Appreciates and understands REACH's health and environmental goals
- Costly: need for cost-benefit analyses
- Workability: complex and burdensome
- Impact on EU competitiveness and innovation
- Non-tariff trade barrier for the US chemical industry and for US imports to Europe
- Interfere with on-going international efforts
- Technical ability to implement

REACH Chronology (cont.)

Europe

- 2004-05 More than 1000 amendments proposed
- 2005 1st Reading completed in EP
- 2006 Council adopts common position

  Agreement on most points of a scaled back proposal
- 2006 Passed during the 2nd Reading

United States

- 2004 Waxman report published
- 2005 GAO study published
- 2006 UC PRC Green Chemistry report released

REACH Legislation

- Introduces registration and mandatory data requirements for new and an estimated 30,000 existing chemicals
- Transfers responsibility for risk assessment from government to the manufacturers and importers
- Includes downstream uses in the registration and management process

REACH Legislation (cont.)

- Introduces authorization and restriction procedures for the most hazardous chemicals
- Provides greater transparency and public access to information
- Establishes a new European Chemicals Agency

REACH Implementation

- Dec. 2006: REACH was passed by both the European Parliament and the European Council
- June 2007: REACH enters into force
- June 2008: European Chemicals Agency becomes operational. It will be located in Helsinki, Finland and is anticipated to eventually have a staff of 450.
- June - Nov. 2008: Pre-registration of existing substances.

REACH Implementation (cont.)

- Nov. 2010: Registration deadline for ≥1000 ton substances as well as carcinogens, mutagens, and reproductive toxicants produced at >1 ton, and agents very toxic to aquatic organisms produced at >100 tons.
- June 2013: Registration deadline for substances produced in ≥100 tons and substances toxic to the aquatic environment.
- June 2018: Registration deadline for substances produced in quantities of ≥1 ton.

REACH

- Pre-Registration
  - For substances produced in quantities ≥1 ton per year, basic information on the chemical, contact information, the anticipated production volume and registration deadline is to be provided to the new European Chemicals Agency (ECA).

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- Registration
  - For substances produced in quantities ≥1 ton per year, a registration dossier is to be provided to ECA. Based largely on volume, specific information about physicochemical, toxicological and ecotoxicological properties must be included. If additional testing is necessary, a test plan including coordinated animal testing, needs to be submitted.

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- Registration (cont.)
  - Individual downstream uses throughout the supply chain as well as the associated risks and safety measures must be provided.
  - For chemicals ≥10 tons, a Chemical Safety Report must also be provided.

Testing/Data Requirements*

	>1 t/yr	>10 t/yr	>100 t/yr	>1000 t/yr
Physical-chem. data	14	14	17	17
Environmental fate	1	4	10	13
Ecotox. data	2	4	12	16
Mammalian tox.-related data	6	14	18	24

***Note: These numbers are approximate and represent high end estimates as many of the test requirements are conditional.**

REACH

- Evaluation
  - Member states can check compliance and examine testing proposals.
  - Member states may also examine dossiers to evaluate whether a substance presents a risk to humans or the environment.

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- Authorization
  - Required for substances considered to be CMR (carcinogenic, mutagenic or reproductive toxicants), PBTs (persistent, bioaccumulative and toxic), and vPvBs (very persistent and very bioaccumulative).

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- Authorization (cont.)
  - Authorization granted if the manufacturer or importer is able to demonstrate that the risks can be adequately controlled. If not controllable, the chemical must be shown to have compelling socio-economic benefits without suitable alternatives. A research plan is also to be submitted.

REACH (cont.)

- Restriction
  - If a risk is identified as inadequately controlled, a proposal to restrict the use and marketing of a substance can be made by the Commission or a Member State.
  - The final decision on authorization will be taken by the Commission, in consultation with the Member States.

Testing/Data Requirements Under REACH

Physicochemical Tests

- **≥1 Ton**: Physical state, melting/freezing point, boiling point, relative density, vapor pressure, surface tension, water solubility, partition coefficient, flash-point, flammability, explosive properties, self-ignition temperature, oxidizing properties, granulometry.
- **≥100 Tons**: Stability in organic solvents and identity of relevant degradation products, dissociation constant, viscosity

Toxicological Test Examples

- **≥ 1 Ton***: Skin irritation (2 in vitro), eye irritation (1 in vitro), skin sensitization (murine lymph node assay), mutagenicity (1 bacterial gene mutation), acute toxicity (oral)
- **≥10 Tons**: Skin irritation (in vivo), eye irritation (in vivo), mutagenicity (2 in vitro), acute toxicity (inhalation or dermal), repeated dose toxicity (28 days), repro/developmental toxicity screen (1 species), toxicokinetics.

Toxicological Tests (cont.)

- **≥ 100 Tons**: Mutagenicity (1 in vivo), repeated dose toxicity (90 day), developmental (1 in vivo), 2 generation reproductive study.
- **≥1000 Tons**: Mutagenicity study (in vivo), long term toxicity study (≥12 months), reproductive toxicity, two generation study, carcinogenicity study.

- Note: Most test requirements are conditional and are in addition to test requirements at lower levels.

Ecotoxicological and Environmental Fate Test Examples

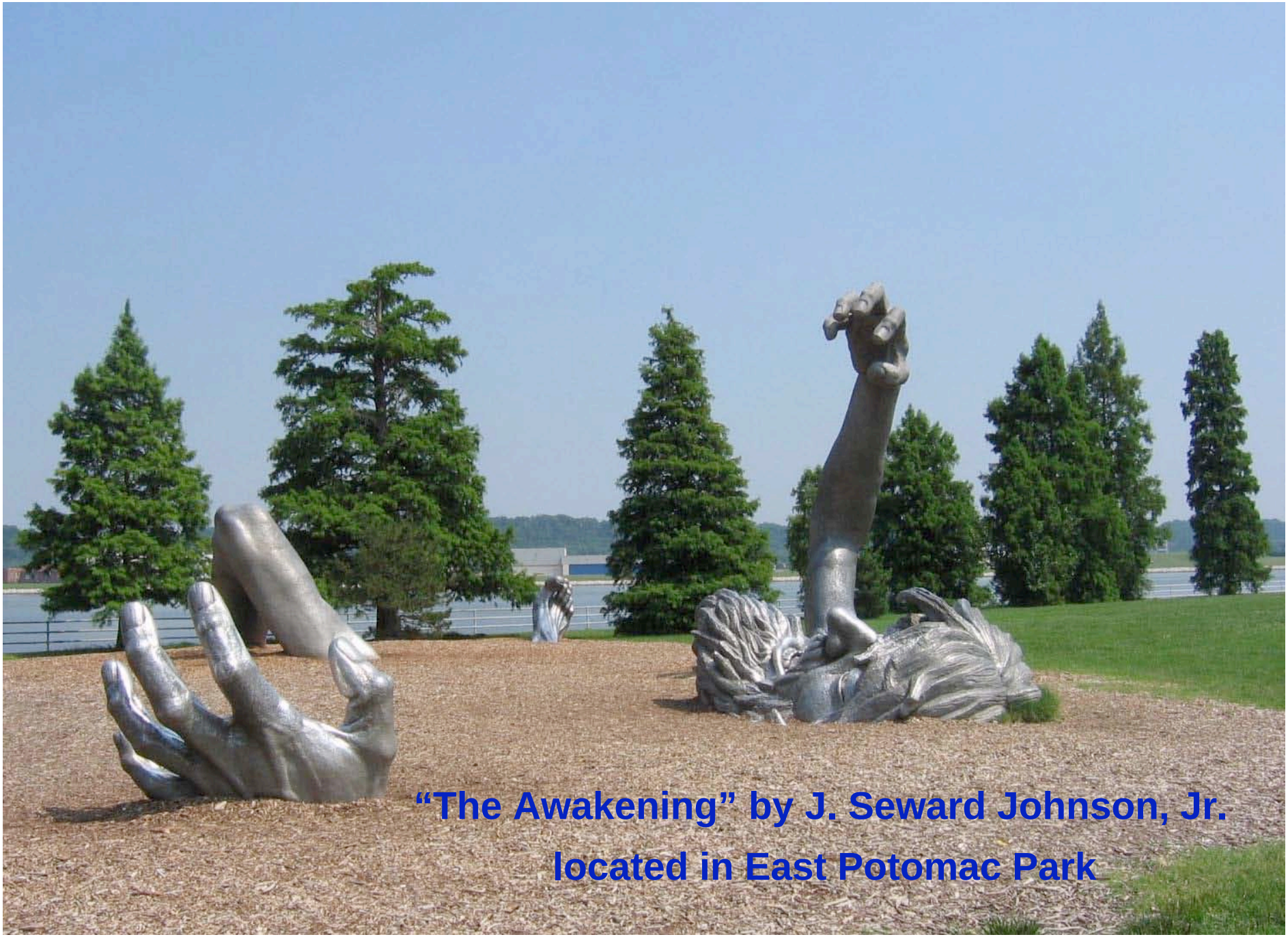
- **≥ 1 Ton**: Aquatic toxicity (short-term test in Daphnia; growth inhibition study in algae), biotic biodegradability.
- **≥10 Tons**: Aquatic toxicity (short-term test in fish; activated sludge respiration inhibition), biotic and abiotic degradation, adsorption/desorption screening

Ecotoxicological and Environmental Fate Tests (cont.)

- **≥ 100 Tons**: Aquatic toxicity - long-term test in Daphnia; toxicity tests in fish (early life stage, short-term test on embryo and early fry stages, and juvenile growth test), bioconcentration in fish, degradation simulated in surface water, soil and sediment, identification of biodegradation products, adsorption/desorption, short-term toxicity to earthworms, soil microbes, plants.
- **≥1000 Tons**: Biodegradation (aerobic & anaerobic), environmental fate, long-term toxicity to terrestrial invertebrates, plants ,sediment organisms, birds

REACH Impacts

- Estimated to involve 30,000 chemicals and most articles manufactured in Europe or imported.
- Direct costs: Best estimates ranged from ~$3.5 to 6.3 billion (<0.1% of sales; some estimates were projected to $50+ billion).
- Benefits: Hard to quantify. Hypothesized to prevent 4500 cancer cases per year with possible overall health savings of up to $50 billion over 30 years.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Questions?

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